IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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Plaintiff,

v.

TEVA PHARMACEUTICALS USA and TEVA PHARMACEUTICAL INDUSTRIES LTD.

Defendants.

Civil Action No. 06-89 (GMS)

ANSWER OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), through its undersigned counsel, hereby answers the Complaint of plaintiff Pfizer Inc. ("Pfizer") as follows. This Answer is based upon Teva USA's knowledge as to its own activities, and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in Pfizer's Complaint.

PARTIES

- 1. Upon information and belief, admitted.
- 2. Upon information and belief, admitted.
- 3. Upon information and belief, admitted.
- 4. Upon information and belief, admitted.
- 5. Upon information and belief, admitted.
- 6. Denied to the extent that Teva Pharmaceuticals USA, Inc. is incorrectly referred to as Teva Pharmaceuticals USA. The allegations of this paragraph are otherwise admitted.

7. Teva USA admits that it is a wholly-owned indirect subsidiary of Teva
Pharmaceutical Industries Ltd. Upon information and belief, Teva USA admits that Teva
Pharmaceutical Industries Ltd. is a corporation or other entity organized and existing under the
laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.
To the extent the allegations of this paragraph go further, they are denied.

JURISDICTION AND VENUE

- 8. Teva USA admits that Pfizer purports to state claims that arise under the patent laws of the United States, United States Code, Title 35, and that Pfizer purports to state claims such that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 9. Teva USA admits that it is a Delaware corporation, and that it does not contest personal jurisdiction in this District. The allegations of this paragraph are otherwise denied.
- 10. Teva USA denies that the activities of Teva USA that Pfizer alleges form the basis for its Complaint have been and remain under the control and direction of Teva Pharmaceutical Industries Ltd. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.
- Teva USA does not contest venue in this District under one of United States Code, Title 28, §§ 1391(c), (d) and 1400(b), but avers that venue should be transferred to the United States District Court for the Southern District of New York pursuant to 28 U.S.C. § 1404(a). To the extent the allegations of this paragraph go further, they are denied.

THE PATENT-IN-SUIT

12. Upon information and belief, admitted.

- 13. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph.
- 14. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph.
- 15. Upon information and belief, Teva USA admits that a Certificate of Correction to the '243 patent issued and is attached to the Complaint as Exhibit B. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in this paragraph
- 16. Teva USA refers to the '243 patent and certificate of correction for their contents.

 To the extent the allegations in this paragraph go further, they are denied.
- 17. Teva USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph.

COUNT 1 (Patent Infringement)

- 18. Teva USA repeats and re-alleges its responses to Paragraphs 1-17 above as if set forth fully herein.
 - 19. Admitted.
 - 20. Admitted.
 - 21. Admitted.
- 22. Teva USA admits that it began shipping azithromycin tablets 250 mg, 500 mg and 600 mg, on, about, or after November 14, 2005, and continues to do so. The remaining allegations of this paragraph are denied.
 - 23. Denied.

- 24. Denied.
- 25. Denied.
- 26. Denied.
- 27. Denied.
- 28. Denied.
- 29. Denied.

COUNT II (Active Inducement of Infringement)

- 30. Teva USA repeats and re-alleges its responses to Paragraphs 1-29 above as if fully set forth herein.
- 31. Admitted that Teva Pharmaceutical Industries Ltd. researched and developed the azithromycin products that are the subject of ANDA Nos. 065153, 065193 and 065150. The allegations of this paragraph are otherwise denied.
 - 32. Denied.
 - 33. Denied.
 - 34. Denied.

<u>COUNT III</u> (Declaratory Judgment of Infringement of the '243 Patent)

- 35. Teva USA repeats and re-alleges its responses to Paragraphs 1 through 34 above as if fully set forth herein.
- 36. Teva USA admits that Pfizer purports to state a claim under the Declaratory Judgment Act; that Teva USA sells and offers for sale its 250 mg, 500 mg and 600 mg

azithromycin tablets in the United States; and that it began shipping on, about, or after November 14, 2005. The allegations of this paragraph are otherwise denied.

- 37. Teva USA admits that it sells and offers for sale its 250 mg, 500 mg and 600 mg azithromycin tablets in the United States, and that it began shipping on, about, or after November 14, 2005. The allegations of this paragraph are otherwise denied.
 - 38. Denied.
 - 39. Denied.

COUNT IV

(Declaratory Judgment of Infringement of the '243 Patent)

- 40. Teva USA repeats and re-alleges its responses to Paragraphs 1 through 39 above as if fully set forth herein.
- 41. Teva USA admits that Pfizer purports to state a claim arising under the Declaratory Judgment Act. The allegations of this paragraph are otherwise denied.
- 42. Teva USA admits that it sells and offers for sale its 250 mg, 500 mg and 600 mg azithromycin tablets in the United States, and that it began shipping on, about or after November 14, 2005. The allegations of this paragraph are otherwise denied.
 - 43. Denied.
 - 44. Denied.

Teva denies that Pfizer is entitled to the relief sought in the "Prayer for Relief" of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE (Noninfringement)

Teva USA's manufacture, use, offer for sale, sale, and/or importation of its 250 45. mg, 500 mg and 600 mg azithromycin tablets pursuant to ANDA Nos. 65-153, 65-193, and 65-150, respectively, has not infringed, does not infringe and will not infringe any valid and properly construed claim of the '243 patent.

SECOND AFFIRMATIVE DEFENSE (Noninfringement)

Teva USA's filing of its ANDA Nos. 65-153, 65-193, and 65-150 was not an act 46. of infringement under 35 U.S.C. § 271(e)(2)(A).

THIRD AFFIRMATIVE DEFENSE (Invalidity)

The claims of the '243 patent are invalid for failure to comply with one or more 47. sections of Title 35, United States Code, including, but not limited to, sections 101, 102, 103, and 112.

FOURTH AFFIRMATIVE DEFENSE (Failure to State a Claim Upon Which Relief May be Granted)

Pfizer has failed to state a claim upon which relief may be granted. 48.

PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that the Court enter judgment against Pfizer to include:

- Dismissal of Pfizer's complaint with prejudice; A.
- Denial of each of Pfizer's requested forms of relief against Teva USA; B.

- C. An award to Teva USA of its reasonable costs and attorneys' fees in connection with this action; and
 - D. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

MORRIS, JAMES, HITCHENS & WILLIAMS LLP

Dated: March 1, 2006

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By:

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of March, 2006, I electronically filed the foregoing document, **ANSWER OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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